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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,506	04/07/97	WEBBER	R 12842

EXAMINER	
HUFF, S	
ART UNIT	**PAPER NUMBER**
1642	29

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DATE MAILED: 09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)
*U S GPO 2000-473-000/44602

Office Action Summary	Application No. 08/833,506	Applicant(s) WEBBER, ROBERT	
	Examiner Sheela J Huff	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

The amendment filed on 8/17/01 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Claim 29 was missing. Therefore, claims 30-42 been renumbered as claims 29-41.

Claims 22-41 are pending.

The substitute specification has been entered.

All of the rejections are withdrawn in view of the cancellation of claims 1-21.

New Grounds of Rejection

Sequence listing

On page 32 the sequence at region 25-42 needs a SEQ ID No.

Claim Rejections - 35 USC § 112

Claims 22-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. In claims ~~22-23~~ 42-43, and ~~29~~ 49, the terminology "regions of human iNOS" renders the claim vague and indefinite. What does applicant mean by "regions"? How many amino acids are there is a "region"?

b. In claim ~~23~~ 43, what does applicant mean by "polymers as artificial antibodies" and "phage display binding sites"? Polymers are polymers (organic compounds) not antibodies,

c. In claim ~~29~~ 49 it is not clear what applicant means by "mimics".

d. In claim ~~22~~ 42, line 1 "a analysis sample" should be --analysis of a sample--.

e. In claims ~~24-25~~ 44 45 and 31, in SEQ Id No. 32 the second to the last amino acid residue is incorrect--"O" is not an amino acid.

f. In claims ~~24-25~~ 44 45 and 31, applicant should use parenthesis for off set the Seq Id No from the actual sequence.

g. In claims ~~24-25~~ 44 45 and ~~31~~ 51, the third sequence needs a SEQ Id No.

h. In claims ~~24-25~~ 44 45 and ~~31~~ 51, SEQ Id No 26 and 29 are the same--is this correct?

i. In claims ~~24-25~~ 44 45 and 31, SEQ ID No. 31 has a "C" as the eighth amino acid residue. According to page 32 of the spec. the C is actually a --S--. Please correct.

j. In claim 27, line 1, "said step of the" should be --said step of detecting the--.

k. In claims 29 and 34-35 the term "revealing" is vague and indefinite. How is it "revealed"? Does applicant mean --detecting--?

l. In claim 41 line 3, SEQ ID No. 121 should be SEQ Id No. 120.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16 and 17 of copending Application No. 08/634332. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to immunoassays. The only difference between the two is that the specific binding entity of the instant invention can be other things in addition to an antibody.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23, 26-28 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/23038 (Moncada et al) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are as applied to claims 1-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant did not indicate how the amendments to the claims overcome this rejection.

Claims 22, 26-28 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95). The reasons for this rejection are as applied to claims 1, 4-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant did not indicate how the amendments to the claims overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims ~~22-23~~ 42-43 ~~26-28~~ 46-48 and ~~39~~ 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda Tojo Medical Journal vol. 65 p. 433 (6/95) or Kobzik et al Am. J. Respir. Cell Mol. Biol. vol. 9 p. 371 (1993) or Fujisawa et al J. Neurochemistry vol. 64 p. 85 (1995). The reasons for this rejection are as applied to claims 1-2, 4-7, 12, 18 and 21 in paper no. 5, mailed 5/8/98.

Applicant did not indicate how the amendments to the claims overcome this rejection.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday and Thursday from 5:30am to 2:00pm.

If attempts to teach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Tony Caputa, can be reached on (703)308-3995.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sjh
9/17/01

Sheela J. Huff
Primary Examiner